

Funding Opportunity For Bridges To Stem Cell Research And Therapy Awards

EDUC 2



REQUEST FOR APPLICATIONS
03.02.21



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Funding Opportunity For Bridges To Stem Cell Research And Therapy Awards

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Objective

The mission of California Institute for Regenerative Medicine (CIRM) is to accelerate stem cell treatments to patients with unmet medical needs.

The overall objective of the Bridges Training Program is to produce well-trained, committed and “ready-to-start” laboratory professionals for both academia and industry to accelerate the discovery, development and delivery of stem cell, gene therapy and related technologies for improving human health. Specific objectives are to:

- Enable training that will significantly enhance the technical skills, knowledge, and experience of a diverse cohort of undergraduate and master’s level students from California’s state universities and community colleges
- Foster a commitment among trainees to the goal of accelerating the delivery of stem cell-based and gene therapy treatments to patients with unmet needs
- Broaden the participation in regenerative medicine of individuals representing the diversity of California’s population
- Create a cadre of technically skilled, stem cell ambassadors with an awareness and appreciation of inequities that impact development of therapies for all
- Promote trainees’ efficient transition to careers in the life sciences and regenerative medicine by directly linking educational programs to organizations and companies focused on stem cell and gene therapy research and related disciplines

Priority will be given to applications that offer matching funds or verified in-kind support and applications that enhance the geographic distribution of training and socio-economic diversity.

Award Information

How is the Bridges Training Program structured?

Each Bridges Training Program will be led by a qualified Program Director based at the awardee, “home” institution, which will be responsible for the management and coordination of all activities supported by the program as well as outreach to and the recruitment of diverse and qualified students. The Bridges program must be integrated into a degree or certificate program at the home institution. Research internships, which are a central component of these programs, will take place at partner or “host” institutions, which are biotech, CRO, CDMO, or pharmaceutical companies, research universities or institutes.

What is the award amount and duration?

The CIRM Governing Board has allocated \$65.7 million to support up to 18 awards for a duration of five years. Each award will provide direct project costs of up to \$3.32M plus 10% indirect costs on eligible expenses, for a total of up to five years. Each award will support up to 10 trainees per year.

How will funds be awarded?

Awards will be made in the form of a grant. CIRM will disburse funds pursuant to a Notice of Award. CIRM will only disburse trainee internship funds upon submission of a signed Intern Appointment Form for an eligible trainee.

What activities will CIRM fund?

1. Trainee Funds

The award will provide up to the following amounts per trainee:

- a. Stipends – up to \$3,000/month during the full-time research internship period of up to one year.
- b. Tuition and fees – up to \$8,000 to the applicant institution for actual educational expenses during the internship period.
- c. Research-related funds – up to \$3,300 for research project costs to the internship host laboratory.
- d. Techniques course fees – up to \$3,000 for fees and expenses (including travel) for a training course in advanced cell culture techniques.
- e. Travel funds – up to \$1,000. These funds must be used in part to cover travel costs to attend an annual CIRM Trainee Meeting. Excess funds may be used to cover other program-related travel for the trainee.

2. Program Administration Funds

Up to \$150,000 per year may be requested to develop and administer the required training activities. Funds may be used for administrative support salaries, planning



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and implementing activities focused on patient and healthcare engagement, community outreach, educational enhancement activities, seminar speakers, outside speakers for courses or workshops, or other activities that enhance the educational value of the program. Up to \$25,000 (of the \$150,000) may be requested for salary support for the Program Director. Up to \$7,000 may be requested for salary support of a faculty advisor or internship coordinator at internship-host institutions. Adequate justification for all Program Administration expenses must be provided.

Eligibility

What types of projects are eligible for funding?

(1) To be eligible, the proposed program must include the following components:

- a. **Patient (or Patient Advocate) and Healthcare Engagement Activities** designed to engage trainees with patients/patient advocates and provide insights into the challenges of developing new cell therapies and drugs. Such activities could include volunteer participation in medical settings (e.g. community clinic, emergency room, etc.), participation in the implementation of blood donation or bone marrow donor screening drives, participation in workshops or seminar programs featuring drug developers, and colloquia or individual interactions with patient advocates.

An additional component of this core activity is that trainees must complete a course on the process for the development and regulation of new therapies, such as GMP manufacturing, Quality, Regulatory Affairs, etc. This could involve a locally offered course, an online course (e.g. a course offered by the Regulatory Affairs Professional Society, RAPS), a series of workshops, or other formal activities required of all trainees.

- b. **Internships at host laboratories**, where trainees participate in hands-on, regenerative medicine-related research involving stem cells, gene therapy and/or other critical research relevant to understanding or treating a human condition or disease.

CIRM will fund internships for a minimum of six months and a maximum of one year. Programs are permitted to have up to two tracks or types of internship (e.g. undergraduate-level internships and Master's level internships), and all internships within a track must be of the same duration in each funded year. Internship research is expected to be a full-time activity for which the trainee is compensated with a stipend and appropriate academic credit (determined by the applicant institution).

Trainees are expected to be enrolled as full-time students during the internship. CIRM will fund up to 10 internships per applicant per year. Applicants are encouraged to expand trainee participation and the size of their programs by involving additional trainees supported from other sources, if funding is available.

- c. **Educational Enhancement Activities** that prepare students for internship research and augment the internship experience.
- d. **Community Outreach and Education Activities** in which trainees participate in educating diverse California communities about stem cells, gene therapy



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and regenerative medicine, and gain awareness of socio-economic issues and disparities around health care and access. Such activities might include making presentations to community groups or to elementary or secondary school classes, participation in local health fairs, preparation and distribution of targeted educational materials, and creating opportunities to communicate medical innovations to diverse communities while gaining insight and awareness of those communities' perspectives and concerns.

- e. **Advanced Cell Culture Techniques Course** that will provide all trainees with hands-on training in methods for working with human stem cells and/or other therapeutically relevant human cell types.
- f. **Advising and Career Development Activities** to equip and assist trainees and Bridges Training Program alumni in advancing to jobs and further opportunities in regenerative medicine for themselves and others.
- g. **A Diversity, Equity and Inclusion Plan** that addresses:
 - How the implementation of the Bridges Training Program will incorporate diverse and inclusive perspectives and experience in the development and implementation of the program.
 - How the grantee institution will conduct outreach and recruit qualified persons for training who are representative of the diverse California population, including, for example, those from different socio-economic backgrounds and those who are the first in their family to attend college.

(2) Must be ready to initiate work on the funded project within 60 days of approval

Given the urgency of CIRM's mission, all approved awardees must initiate work on the funded project within 60 days of approval and authorization for funding by the Application Review Subcommittee of the Independent Citizens' Oversight Committee or upon end date of a preceding Bridges grant.

(3) Application must be accurate and complete

All required components of the application must be completed and may not contain false or inaccurate information.

(4) Applicant must be in "good standing"

In order to be eligible to apply for CIRM funding, an applicant must certify that it is in good standing, as follows:

- a. Non-Profit (in existence for less than five years):
 - (i) The applicant's Chief Executive Officer, Chief Financial Officer, and Program Director must not have been convicted of, or currently under investigation for, crimes involving fraud/misappropriation; and
 - (ii) The applicant must have accounting systems in place that are capable of tracking CIRM funds.
- b. The Program Director or key personnel must not be currently under investigation for research misconduct by the applicant institution or a funding agency, and must not be currently debarred by HHS Office of Research Integrity.



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Applicant institutions must be California public universities or colleges, or private, non-profit academic institutions in California that are accredited by the Western Association of Schools and Colleges (WASC) and which did not receive a CIRM-funded Major Facility or Shared Research Laboratory Award under Proposition 71.

Non-profit means either: (1) a governmental entity of the State of California; or (2) a legal entity that is tax exempt under Internal Revenue Code section 501(c)(3) and California Revenue and Taxation Code section 23701d. Additionally, since the Bridges Awards must be associated with an appropriate comprehensive educational program, applicant institutions must have either 1) a Bachelor's or Master's degree program in Cell and Molecular Biology, Biotechnology, Biomedical Sciences or equivalent discipline, or 2) a Certificate or Associate degree program in Biotechnology or Biomedical Technology or equivalent.

Each eligible applicant institution may submit only a single application. The applicant institution may choose to collaborate with one or more additional institutions that would otherwise also be eligible to compete in order to provide broader program access to candidate trainees/interns. Collaborating institutions must meet the above institutional eligibility criteria and may not separately submit an application.

Who can serve as the Program Director (PD)?

To be eligible, the PD must satisfy the following requirements:

- Must be a full-time faculty member of the applicant organization or be accountable for the conduct of the proposed project to the applicant organization through a formal contract
- Must commit a minimum of 5% effort to the program.
- Must be authorized by the applicant organization to assume the responsibilities of the PD
- Must not currently have another application pending review or approval under this funding opportunity

Who can participate as a host institution?

Internship-host laboratories can be at California non-profit doctorate granting research universities or research institutes or at California laboratories of for-profit biotech or pharmaceutical companies, including CROs or CDMOs. Internships cannot occur at the applicant institution.



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Schedule and Deadlines

Applications Due	April 22, 2021, 2:00pm Pacific Time
Grants Working Group (GWG) Review	Approximately 60 days post submission
ICOC Review and Approval	Approximately 90 days post submission
Award Start	Within 60 days of award approval (i.e., approximately 130 days post submission) or end of preceding Bridges grant

Application Review Information

What is the process for evaluating an application?

Eligibility Review

CIRM will assess whether the applicant and proposed program meets eligibility requirements under this RFA. If CIRM determines, in its sole discretion, that an applicant or proposed program does not meet the eligibility requirements, CIRM will notify the applicant of its decision, and the application will not be reviewed.

Scientific Review

The scientific and educational merit of each application will be assessed by the CIRM Grants Working Group (GWG), which is composed of fifteen subject matter experts from outside California, seven patient advocate members of the Independent Citizens Oversight Committee (ICOC), and the Chair of the ICOC. The list of scientific members who may participate in the GWG review can be found at http://www.cirm.ca.gov/WorkingGroup_GrantsReview. The composition of the ICOC can be viewed at <http://www.cirm.ca.gov/GoverningBoard>.

The fifteen participating scientists on the GWG will evaluate the applications and score them according to scientific and technical merit, applying the review criteria described below. The GWG scientific members will score each application and the full GWG will make funding recommendations to the ICOC's Application Review Subcommittee.

The ICOC's Application Review Subcommittee will make final funding decisions giving consideration to the GWG recommendations and any CIRM team recommendations.

Priority will be given to applications that offer matching funds or verified in-kind support and applications that enhance the geographic distribution of training and socio-economic diversity.



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Confidentiality

CIRM's confidentiality and conflict screening rules apply to everyone who will have access to applications or who will attend any review meeting in which confidential information is discussed, including but not limited to CIRM team members, reviewers and members of the ICOC. (Per Gov. Code §6254.5(e) non-public records may be disclosed to government agencies under confidentiality agreements.)

How will the educational and technical merit of an application be evaluated?

Scientific members of the GWG will evaluate and score applications based on the following key criteria:

1. Does the proposed program hold the necessary significance and potential for impact?

Is the proposed training program likely to have a meaningful, positive impact on trainees' career development in stem cell science and awareness of therapy development and patient needs? Is the program likely to foster a commitment among trainees to the CIRM Mission of accelerating the delivery of stem cell-based therapies to patients? Is the program likely to impact trainees representing the broad diversity of California's population?

2. Is the training program well planned and designed?

Is the training program appropriately planned and designed to provide all trainees a quality, first-hand experience in stem/progenitor cells, gene therapy and/or other critical laboratory research relevant to understanding or treating a human condition? Are there robust plans in place to support all required core training activities? Does the program provide a suitable mentoring and career development plan for all Bridges trainees and alumni that enables career advancement? Have adequate mechanisms and procedures been established for tracking trainee progress after completing the program? Does the program propose a well-considered diversity, equity and inclusion plan?

3. Is the proposed program practical and achievable?

Does the program have access to all the necessary resources, including personnel and key partnerships, to implement and carry out the proposed training program? Is the program director appropriately qualified to manage and lead the training program? Does the institutional commitment and track record support achievement of program objectives? Are appropriate mechanisms established for the recruitment of qualified students with diverse backgrounds?



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Application Components and Submission

How does one apply?

Applications must be completed online using the CIRM Grants Management Portal at <https://grants.cirm.ca.gov>. Any prospective Program Director (PD) must create a login in the system to access application materials and apply. Applications are available in the system only to the PD. A PD may submit only a single application in response to this RFA.

Applications are due by 2:00 PM (Pacific Time) on April 22, 2021.

What is required to prepare a complete application?

The Grants Management Portal provides instructions for completing all the necessary components and submitting a final application. The application is designed to collect information necessary to appropriately evaluate the proposal and for CIRM to rapidly initiate an award if approved for funding. Applicants are required to indicate key personnel involved in the program, describe how the program will address the RFA objectives, provide a detailed plan of proposed activities, summarize internship host lab opportunities and include letters confirming support and commitment of the applicant institution and any partnering organizations. If the program is proposed to have two tracks (e.g. undergraduate trainees and Master's trainees), the proposal must describe key differences in the program activities, specific to the individual tracks.

The main body of the proposal contains the following sections:

- 1. Program Summary and Overall Program Design:** description of the proposed program of training including the level of training, the numbers of trainees, the scientific curriculum, the nature of the educational program with which the internships will be integrated.
- 2. Trainee Selection and Internship Placement:** description of how trainees will be recruited and selected for the program and how trainees will be placed in internships.
- 3. Patient and Healthcare Engagement Activities:** description of planned activities including specific details about scope and duration of activities and nature of trainee involvement, including a description of the required coursework in the development and regulation of new therapies.
- 4. Educational Enhancement Activities:** description of planned activities including specific details and duration of activities.
- 5. Community Outreach and Education Activities:** description of activities focused on educating diverse California communities and groups about stem cell biology and regenerative medicine.
- 6. Advanced Cell Culture Techniques Course:** description of the required course or equivalent training activity providing hands-on experience with human stem cells and/or other therapeutically relevant human cell types.
- 7. Mentoring, Advising and Trainee Assessment:** description of how Bridges trainees and alumni will be mentored, advised and assessed.
- 8. Program Leadership and Administration:** summary of the program leadership including the Advisory Committee and qualifications of the Program Director. Each



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program must create an Advisory Committee that establishes policies and guides ongoing planning and performance of the program.

9. Prior Program Track Record and Outcomes: description of prior CIRM Bridges Training Program or other similar program including quantitative information about program outcomes.

10. Internship-host Institutions: list of internship-host institutions with which agreements or arrangements for trainee placement have been established or planned.

11. Diversity, Equity and Inclusion Plan: a description of 1) how the implementation of the Bridges Training Program will incorporate diverse and inclusive perspectives and experience in the development and implementation of the program; and, 2) how the grantee institution will conduct outreach and recruit qualified persons for training who are representative of the diverse California population, including, for example, those from different socio-economic backgrounds and those who are the first in their family to attend college. Because CIRM is prohibited from taking race, ethnicity, national origin and gender into account in making grant decisions, we request that you refrain from including specific reference to race, ethnicity, national origin, or gender in your description.

Who are Key Personnel?

In the application, we ask you to identify by name pertinent Key Personnel and their specific roles in the program. Key Personnel include the Program Director and any key administrative personnel. Do not include internship-host mentors, advisory committee members, or internship host coordinators in this section.

What should one know before preparing the budget?

All budgetary requests must be indicated on the online application form. Limits for each budget category are indicated above (Award Information: What Activities Will CIRM Fund?) and must be observed. Budget justification for "Program Administration Funds" should provide sufficient detail to allow evaluation of the appropriateness of the costs in relation to the activities proposed. Budget justification for "Trainee Funds" is not required; however, number and type of trainee positions should be justified in the "Program Summary and Overall Program Design" section of the proposal.

How much can an applicant claim for indirect costs?

Indirect costs will be limited to 10% of the total direct costs (Trainee Funds and Program Funds) less the costs for tuition and fees. For this program, CIRM will not allow the applicant institution to incur additional Indirect Costs on any subcontract costs proposed for the project.

Award Administration

Issuance of Award

A CIRM Bridges Training Program award is issued via a Grant, which is the formal contract that defines the terms and conditions of an award and documents the commitment of funds from CIRM.

CIRM will adjust the award start date for a Bridges Training Program award to coordinate with the academic year calendar of the applicant institution. For recipients of a Bridges Training Program award who previously received a Bridges Training Program Grant under Proposition 71, the new award must begin after the end of the previous Grant term.

Reporting

Grantees will be required to provide annual written progress and financial reports to CIRM. Bridges Training Programs also will be required to submit Intern Appointment Forms describing the planned laboratory placement, mentor and research activities/project for each trainee prior to start of the internship. CIRM will only disburse trainee internship funds upon submission of a signed Intern Appointment Form for an eligible trainee.

Fund Carry-forward and No-Cost Extensions

CIRM allows carry-forward of any obligated trainee funds from one grant year to the next. All unobligated trainee funds at the end of each trainee internship must be returned to CIRM and cannot be used to fund additional internships, additional program administration funding or for any other purpose unless specifically approved in advance by CIRM for exceptional circumstances. CIRM will allow carry-forward of unobligated program administration funds from one grant year to the next in order to allow use of those funds in a way that best serves the trainees.

No-cost extensions (NCEs) are only permitted under exceptional circumstances, where an extension would facilitate the completion of a trainee's normal internship term; such an extension would require specific approval by CIRM.



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